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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/689,281 10/11/00 COSENZA

S 6056-277

HM22/0705
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EXAMINER

BAHAR, M

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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| | | | |
|------------------------------|-------------------------------|---------------------------------|--|
| Office Action Summary | Application No. 09/689,281 | Applicant(s) CONSENZA ET AL. | |
| | Examiner Mojdeh Bahar | Art Unit 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
 4a) Of the above claim(s) 8-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 12-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|--|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 20) <input type="checkbox"/> Other: |

Detailed Action

Applicant's response to the election of species requirement and remarks submitted June 13, 2001 is acknowledged.

Applicant's election with traverse of specie 4-carboxystyryl-4-chlorobenzylsulfone in Paper No. 7 submitted June 13, 2001 is acknowledged. Applicant's traversal on the ground that there is unity of invention among the different species of compounds has been considered, but is not found persuasive. Unity of invention (single general inventive concept) is the basis of restriction only in applications filed under 35 U.S.C. 371(national stage applications) cases.

The specie election of April 10, 2001 is based on the diverse classification of the specie encompassed by the claims, see particularly pages 2 and 3 of the specie election requirement. As shown in the restriction requirement of April 10, 2001 the compounds encompassed by the claims fall into different subclasses. The search for all possible compounds is therefore an undue burden on the office. Note that the search is not limited to patent files.

The requirement is still deemed proper and is therefore made FINAL.

Claims 8-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected specie, there being no allowable generic or linking claim. Applicant timely traversed the specie election requirement in Paper No. 7.

The search for species of active compounds herein has been extended to include the styryl sulfone compound, E-4-fluorostyryl 4-chlorobenzyl sulfone.

The claims have been examined insofar as they read on the elected specie and the additional specie discussed immediately above.

Claim Rejections - 35 USC § 112

Art Unit: 1617

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some types of cancer, does not reasonably provide enablement for “treating cancer” in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Given the current state of the art, the treatment of all cancers broadly is unpredictable. One of ordinary skill in the art would not believe that one compound could treat all types of cancer with a single therapeutic agent. Decisional law would seem to indicate that when the utility in question is sufficiently unusual an examiner is justified in requiring substantiating evidence, *In re Buting*, 163 USPQ 689 (1969). Moreover, one of ordinary skill in the art would not know which cancers could appropriately be treated with the claimed compounds and would be required to perform undue experimentation to determine the effectiveness and suitability of the claimed compounds in the treatment of different types of cancer. The Skilled Artisan would view cancer as a group of maladies not treatable with one medicament or therapeutic regimen.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "a compound according to claim 3" in line 1. There is insufficient antecedent basis for this limitation in the claim. Note that claim 3 recites a method. Furthermore, claims 5-7 recite the limitation "a/the method according to claim 4" in line 1. There is insufficient antecedent basis for this limitation in the claim.

In order to expedite prosecution, claims 4-7 have been herein examined as method of use claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-7 are rejected under 35 U.S.C. 102(a) as being anticipated by Reddy et al. WO 99/18608.

Reddy et al. WO 99/18608 discloses a compound of general formula I, II and III (encompassing both E and Z configurations) employed in a method of treating breast and prostate tumor cells, and induce apoptosis of such tumor cells while sparing normal cells, see claims 1-9 and abstract.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reddy et al. WO 99/18608 and Griggs (Embase Abstract AN 1998287056).

Reddy et al. WO 99/18608 teaches a compound of general formula I and II and III (encompassing both E and Z configurations) employed in a method of treating breast and prostate tumor cells, and induce apoptosis of such tumor cells while sparing normal cells, see claims 1-9 and abstract.

Reddy et al. WO 99/18608 does not teach a method comprising the administration of compound of general formula I and II and III (encompassing both E and Z configurations) prior to the administration of mitotic phase cell cycle inhibitor or topoisomerase inhibitor.

Griggs (Embase Abstract AN 1998287056) teaches that cytoprotective agents reduce treatment-related toxicity of anticancer therapy. Griggs specifically teaches the employment of ~~cytotoxic~~ ^{cytoprotective} agents with paclitaxel, see abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ anticancer paclitaxel along with a cytoprotective agent such as the styryl sulfone compounds of Reddy et al.

One of ordinary skill in the art would have been motivated to employ anticancer paclitaxel along with a cytoprotective agent such as the styryl sulfone compounds of Reddy et al. because both compounds are known to be effective in treating cancer. It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be useful for the very same purpose, *In re Kerkhoven*, 205 USPQ 1069, 1072 (CCPA 1980). Further, the optimization of regimens is within the purview of the skilled artisan.

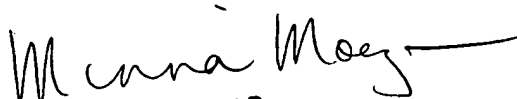
The elected specie 4-carboxystyryl-4-chlorobenzylsulfone is allowable over prior art. Therefore the methods of both claim 1 and 18, employing the elected specie, 4-carboxystyryl-4-chlorobenzylsulfone is not seen to be taught or fairly suggested by the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 on Monday, Tuesday, Thursday and Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
June 28, 2001


MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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